

**REMARKS**

This Amendment, filed in reply to the Office Action dated September 12, 2008, is believed to be fully responsive to each point of objection and rejection raised therein.

Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 1, 3-7, 16 and 18-22 are rejected. Claims 3, 4, 7, 18, 19 and 22 are canceled herewith, without prejudice or disclaimer. Claims 1, 5, 6, 16, 20 and 21 are amended herewith. Claims 1 and 16 are amended herewith to incorporate the subject matter of Claims 4 and 19, respectively, that is, to recite that the whey protein component is “at least one selected from the group consisting of a whey protein isolate, a whey protein concentrate,  $\beta$ -lactoglobulin,  $\alpha$ -lactalbumin, and a whey protein hydrolysate.” Support for such an amendment can also be found on page 5, lines 22-23, of the specification as originally filed. The amendments to Claims 5, 6, 20 and 21 are solely to improve clarity.

No new matter is added by way of this amendment. Entry and consideration of this amendment are respectfully requested.

**Claim to Priority**

Applicants thank the Examiner for acknowledging Applicants' claim to foreign priority, and for indicating that a certified copy of the priority document, namely JP 2002-350200, filed December 2, 2002, has been received.

**Claims 1, 5, 6, 16, 20 and 21 are Definite Under 35 U.S.C. § 112**

On page 2 of the Office Action, Claims 1, 3-7, 16 and 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

1. In one aspect of the rejection, the Office contends that recitation of “whey protein component” in Claims 1 and 16 is unclear.

Initially, Applicants note that Claims 3, 4, 7, 18, 19 and 22 are canceled herewith, mooting the rejection of these claims.

Turning to the substance of the rejection, whilst Applicants maintain that one of ordinary skill in the art would readily ascertain the bounds of such a phrase, rendering the claims definite, solely in the interest of compacting prosecution, and without acquiescing to the merits of the rejection, Applicants herewith amend Claims 1 and 16 to incorporate the recitation in Claims 4 and 19, respectively, that the whey protein component is “at least one selected from the group consisting of a whey protein isolate, a whey protein concentrate,  $\beta$ -lactoglobulin,  $\alpha$ -lactalbumin, and a whey protein hydrolysate.” Applicants respectfully submit that the amendment overcomes this aspect of the rejection.

2. In a second aspect of the rejection, the Office contends that recitation of “decomposition product of whey protein” in Claims 3, 7, 18, and 22 is unclear.

Applicants note that Claims 3, 7, 18 and 22 are canceled herewith without prejudice or disclaimer, mooting this aspect of the rejection.

3. In a third aspect of the rejection, the Office contends that Claims 5 and 6 are indefinite because recitation of “comprises” allows for the inclusion of additional elements. The Office also asserts that Claims 20 and 21 are indefinite for the same reason.

Solely in the interest of advancing prosecution, and without acquiescing to the merits of the rejection, Applicants herewith amend Claims 5, 6, 20 and 21 to remove the term

“comprises.” Applicants respectfully submit that such amendments overcome this aspect of the rejection.

Withdrawal of the indefiniteness rejections is respectfully requested.

**Claims 16, 20 and 21 are Patentable Under 35 U.S.C. § 102**

On page 3 of the Office Action, Claims 16 and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Brantman, of record.

In making the rejection, the Office takes the position that recitation of “comprises” in Claim 16 is reasonably interpreted to allow for the inclusion of additional compositions, *or* additional components within the composition of the claimed method.

The Office asserts that Brantman discloses a composition consisting essentially of carnitine, isoleucine, leucine, valine, glutamine, and a whey protein, adapted for use with water as a diet supplement for facilitating the adaptation of skeletal muscle and liver to a program of strenuous exercise, citing column 7, lines 30-50. The Office also asserts that Brantman discloses a method of supplementing the diet of an athlete by having the athlete drink a solution consisting essentially of leucine, isoleucine, valine, glutamine, and a whey protein, citing column 6, lines 42-53 and Claims 16, 18, 19 and 22. The Office also asserts that Brantman discloses the concentrations of leucine, isoleucine, valine and glutamine recited in Claims 20 and 21.

Applicants respectfully disagree, and traverse the rejection in view of the following remarks.

Initially, Applicants note that Claims 18, 19 and 22 are canceled herewith, mooted the rejection of these claims.

Turning to the substance of the rejection, Applicants note that Claim 16 as examined recites “[a] method of sustainably treating muscular fatigue, which comprises administering a composition consisting of leucine, isoleucine, valine, glutamine and a whey protein component to a subject in need of sustained treatment of muscular fatigue ...” (Emphasis added.) In other words, while recitation of “comprising” in Claim 16 allows for the inclusion of additional process steps, such as the administration of another composition, Applicants note that the composition of Claim 16 nevertheless “consists of” leucine, isoleucine, valine, glutamine and a whey protein component. Accordingly, Applicants strongly, but respectfully, disagree that Claim 16 is properly interpreted to allow the inclusion of any additional component *within the composition recited in the claimed method*. Applicants respectfully submit that such an interpretation runs counter to established claim construction law.

For example, Applicants invite the Examiner to review the Court’s holding in *Mannesman Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986), wherein it was held that the phrase “consists of,” when appearing in the body of a claim, rather than immediately following the preamble, limits only the element set forth in that clause. The Court held that other elements are not excluded from the claim as a whole. Thus, consistent with relevant case law, Applicants note that while recitation of “comprising” in the preamble of Claim 16 allows for additional method steps, the composition recited in the claim nevertheless “consists of” leucine, isoleucine, valine, glutamine and a whey protein component. Because all the compositions of Brantman contain leucine, isoleucine, valine, glutamine, a whey protein component, and at least carnitine, and thus do not consist of leucine, isoleucine, valine, glutamine and a whey protein component, as claimed, Brantman cannot disclose administering a composition consisting of leucine, isoleucine, valine, glutamine and a whey protein component

for any purpose, much less to a patient in need of sustained treatment of muscular fatigue. For this reason alone, Brantman do not anticipate Claims 16, 20 and 21.

Further, Applicants maintain that Brantman do not disclose sustainably treating muscular fatigue in a subject in need of sustained treatment of muscular fatigue, as claimed. As would be recognized by those of skill in the art, and as acknowledged by the Office, the disclosure of Brantman is directed to the promotion of muscle adaptation to strenuous exercise. Brantman disclose that the mechanism for promoting muscle adaptation is “to spare muscle protein and especially muscle BAA by providing the very substrate which is being utilized at the expense of muscle mass as well as liver protein.” (Emphasis added.) Column 3, lines 23-26. Accordingly, Brantman does not disclose the *treatment* of muscular fatigue as claimed, but rather, only its prevention. For this reason also, Brantman does not anticipate Claims 16, 20 and 21.

Withdrawal of the rejection is respectfully requested.

**Claims 1, 5 and 6 are Patentable Under 35 U.S.C. § 103(a)**

On page 4 of the Office Action, the Office rejects Claims 1 and 3-7 under 35 U.S.C. 103(a) as being unpatentable over Brantman, of record.

In making the rejection, the Office asserts that Brantman discloses a composition consisting essentially of carnitine, isoleucine, leucine, valine, glutamine, and a whey protein. The Office also asserts that Brantman discloses a method of supplementing the diet of an athlete by having the athlete drink a solution *consisting essentially of* leucine, isoleucine, valine, glutamine, and a whey protein. The Office also asserts that Brantman discloses the concentrations of leucine, isoleucine, valine and glutamine recited in Claims 20 and 21.

However, the Office acknowledges that Brantman does not disclose a composition consisting of leucine, isoleucine, valine, glutamine, and a whey protein, as claimed.

In an attempt to rectify the deficiencies of Brantman, the Office asserts that one of ordinary skill in the art would readily have omitted carnitine from the composition of Brantman, and expected the resulting composition to be successful in improving fatigue *during* exercise, because Brantman allegedly discloses that a composition consisting essentially of branched amino acids and a whey protein promotes muscle adaptation to strenuous exercise in a person.

The Office asserts that Brantman discloses that BAAs function to remove lactate from muscle, which would reduce and/or prevent muscle fatigue. Further, the Office appears to believe that one of ordinary skill in the art would readily consider that a composition consisting of glutamine, isoleucine, leucine, valine, and whey protein is sufficient to provide therapeutic benefit, by providing branched amino acids that are necessary for removing lactate from muscle, and stimulating protein synthesis in skeletal muscle and in liver.

Applicants respectfully disagree, and traverse the rejection in view of the following remarks.

Applicants respectfully disagree that one of ordinary skill in the art would readily have modified the composition of Brantman to omit carnitine, as is asserted in the rejection, in view of the fact that Brantman teaches away from such a composition.

Specifically, Brantman disclose that carnitine plays a critical role in protecting against the toxic effects of ammonia. See column 3, lines 64-67. Further, in this very same portion, Brantman state that “[a]mmonia is generated during catabolism of amino acids, such as occurs during strenuous exercise, and is toxic. The ready removal of ammonia from muscle is thus desirable.” (Emphasis added.) Further, because the BAAs in the composition of Brantman are

added to ““spare” muscle protein and especially muscle BAA by providing the very substrate which is being utilized at the expense of muscle mass” (see column 3, lines 23-26), one of ordinary skill in the art would readily recognize that the BAAs in the composition of Brantman, which are added and catabolized so as to “spare” catabolism of muscle BAAs, would produce toxic ammonia, and thus impair prevention of muscle fatigue. Accordingly, in view of the disclosure in Brantman of the criticality of carnitine in protecting against the toxic effects of ammonia (which ammonia would be produced, in part, by the BAAs in the composition of Brantman), Brantman teach away from producing such a composition lacking carnitine such that one of ordinary skill in the art would not have possessed any motivation to arrive at the presently claimed invention. Accordingly, Brantman do not render obvious Applicants’ claimed invention.

Withdrawal of the rejection is respectfully requested.

### Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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